In re Applicant:	§	
	§	
Amit Gal-On	§	
	§	
Serial No.: 09/647,952	§	
	§	
Filed: Dec 9, 2000	§	Group Art Unit: 1638
	§	
	§	
For: Recombinant Potyvirus Construct	§	Attorney
And Use Thereof	§	Docket: 1686/12
	§	
	§	
Examiner: DR. GEORGIA HELMER	§	

TRANSMITTAL OF APPEAL BRIEF

Commissioner of Patents and Trademarks
Alexandria, VA 22313

Dear Sir:

Transmitted herewith in triplicate is a corrected APPEAL BRIEF in this application with respect to the Notice of Appeal filed on January 15, 2004.

The fee for Appeal Brief was submitted upon filing of the Appeal Brief on March 5, 2004. If however, this fee was not charged to our account, authorization is hereby granted to charge Account No. 06-2140 any additional fees required. A duplicate copy of this transmittal letter is attached.

Respectfully submitted,

Mark M. Friedman
Attorney for Applicant
Registration No. 33,883

Date: January 12, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant: §
§
    GAL-ON ET AL. §
§
Serial No.: 09/647,952 §
§
Filed: December 06, 2000 §   Group Art Unit: 1638
§
For: RECOMBINANT POTYVIRUS §   Attorney
      CONSTRUCT AND USE §   Docket: was 1268-107
      THEREOF §   now 1686/12
Examiner: DR. GEORGIA HELMER §

Commissioner of Patents and Trademarks
Alexandria, Virginia 22313
ATTENTION: Board of Patent Appeals and Interferences

APPELANT'S SUPPLEMENTARY BRIEF

Dear Sir:

This is in furtherance of the Notice of Appeal filed in this case on January 15, 2004 and of the Appeal Brief filed on March 05 2004. The Examiner withdrew the finality of the office action in a new non-final Office Action mailed on May 19, 2004. This supplementary brief constitutes a request for re-instatement of the appeal as set forth in MPEP 1208(b)(2)(ii).

The fees required under § 1.17(f) and any required petition for extension of time for filing this brief and fees therefore are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate.

This brief contains these items under the following headings and in the order set forth below:

I.   REAL PARTY IN INTEREST

II.   RELATED APPEALS AND INTERFERENCES

III.   STATUS OF CLAIMS

IV.   STATUS OF AMENDMENTS

V.   SUMMARY OF INVENTION

VI.   ISSUES

VII.   GROUPING OF CLAIMS

VIII.   ARGUMENTS

   X   OBJECTIONS ACCORDING TO 37 CFR § 1.75 (c)

   X   REJECTIONS UNDER 35 U.S.C. §112

   X   REJECTIONS UNDER 35 U.S.C. §102

IX.   APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

X.   APPENDIX OF EVIDENCE

XI.   APPENDIX OF RELATED PROCEEDINGS

I. REAL PARTY IN INTEREST

The real party in interest in this case is:

Virogene Ltd.

Hod Ha'Sharon

Israel

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences in this case.

III. STATUS OF CLAIMS

Claims 1,2,6, 10-12, 15 and 20 are currently pending and stand rejected.

All other claims have been cancelled.

IV. STATUS OF AMENDMENTS

In a response [filed 30 April, 2003] to a previous non-final rejection, claims 1,2,6,10,11, 12, 15 and 20 were amended.

In a final action dated July 30, 2003, the Examiner acknowledges these amendments.

V.   SUMMARY OF INVENTION

The present invention generally relates to a recombinant potyvirus infectious nucleic acid construct useful for providing protection against viral infection in plants and to a recombinant virus harboring said construct. More specifically, the present invention relates to a recombinant potyvirus infectious construct containing an HC - Pro gene whose sequence coding for the conserved FRNK box contains an (Arg) to Isoleucine (Ile) substitution.

Most relevant to the current appeal are those embodiments of the invention which employ a ZYMV recombinant potyvirus infectious nucleic acid construct.

The present invention further relates to a method for the production of a mild strain of potyvirus utilizing the above mentioned construct and to a method for protecting plants from viral infection and for transient expression of foreign nucleic acid (genes) in plants, using said construct. Preferably, the present invention relates to a method for cross protection of cucurbits against ZYMV infection.

VI.   ISSUES

The issues presented for review are as follows:

Objections to claims 6, 11, 12 and 20 according to 37 CFR § 1.75 (c) and MPEP § 608.01 (n) as failing to meet the requirement for alternative language.

Rejection of claims 1, 2, 6, 10-12, 15 and 20 as being indefinite according to 35 U.S.C. 112, second paragraph.

Rejection of claims 1-6, 10-12, 15 and 20 as being anticipated by Huet et al., (*Mutations in the helper component protease gene of zucchini yellow mosaic virus affect its ability to mediate aphid transmissibility*, J. General Virology (1994) 75:1407-1414; henceforth, "Huet") under 35 U.S.C. 102(b).

VII.   GROUPING OF CLAIMS

For purposes of the objections according to 37 CFR § 1.75 (c) and MPEP § 608.01 (n):

claims 6, 11, 12 and 20 are grouped together.

For purposes of the §112, second paragraph rejections:

independent claim 1 and dependent claims 2, 11, and 15 are grouped together and will stand or fall as a group;

dependent claims 6, 10, 12 and 20 are each grouped separately and their separate evaluation is respectfully requested.

For purposes of the §102(b) rejections:

independent claim 1 and dependent claims 2, 11 and 15 are grouped together and will stand or fall together;

dependent claims 6, 10, 12 and 20 are each presented separately and may stand independently of the other claims.

VIII.   ARGUMENTS

OBJECTIONS ACCORDING TO 37 CFR § 1.75 (c)

AND MPEP § 608.01 (n)

The Examiner has objected to multiply dependent claims 6, 11, 12 and 20 citing 37 CFR § 1.75 (c) and MPEP § 608.01 (n) which deal with multiply dependent claims. Specifically, the Examiner has objected to the format "*any of* claims X,Y *and* Z" as a means of indicating alternative (i.e. "or") dependence.

The Examiner's objection is not well taken. MPEP § 608.01 (n) clearly states:

> *One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only.* (emphasis added)

37 CFR § 1.75 (c) contains similar language:
> *"(c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only.* ..."(emphasis added)

Webster's New world Dictionary (Second College edition (1976) William Collins + World Publishing Co. Inc.) defines any as:
> *"one, no matter which, of more than two"*

Thus, using the commonly accepted definition of any, it is clear that a multiply dependent claim in the form "*any of* claims X,Y *and* Z" refers to each of claims X,Y and Z alternatively. For this reason, such a claim is counted as three claims for purposes of fee caluculation. The triple payment is reflective of the Examiner's effort in evaluationg three alternative claims.

Thus, Applicant respectfully, but firmly, assrts that the language of claims 6, 11, 12 and 20 as currently on file meets the criteria of referring to other claims *"in the alternative only"* as required by the MPEP and 37 CFR. The linguistic formula employed is analagous to that found in Markush groups which employ the word "and" although they describe "or" logic. The Examiner's objection is refuted.

All objections are refuted. If the appeal board chooses to uphold the Examiner's objection(s), a clear assurance that use of the word "or" in a claim will not compromise the legal validity of the claim is respectfully requested. Once such an assurance is of record in this case, Applicant would, in order to expedite prosecution, consider making the requested linguistic changes.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 1, 2, 6 and 10-12, 15 and 20 under 35 U.S.C. §112, second paragraph as being indefinite because the term "single mutation" is indefinite in the absence of a "frame of reference".

The Examiner cites Rieger et al. [Glossary of Genetics and cytogenetics, 1976] to establish that:

> *".... the standard of reference for a mutant is the so called wild type, either the state of organisms as they are found in nature or arbitrarily chosen."*

Applicant notes, for the record, that it is only in the current office action that it became clear that a frame of reference is being requested for the entire genomic sequence.

With respect to independent claim 1 and dependent claims 2, 11, and 15, the Applicant concedes that no frame of reference has been established for all of the species of potyvirus.

With respect to dependent claims 6, 10 and those portions of claims 12 and 20 which depend therefrom, the Examiner's rejection is not well taken. Throughout the prosecution, the Examiner has relied heavily upon Huet et al. (1994; J. Gen. Virol (75); 1407-14; hereinafter Huet).

Huet is currently the sole prior art reference employed by the Examiner in formulating a 102 rejection (see below). During a recent telephone interview [summary attached as appendix A], the Examiner was made aware that Huet cited, in 1994, a published wild type sequence for ZYMV (Balint et al. (1990) Proceedings of the VIIIth International Congress of Virology (abstract) Berlin; p472).

Applicant asserts Huet's reference to Balint et al (1990) indicates that the required frame of reference for claim 6 and all claims which depend therefrom was widely available and generally acknowledged by those of ordinary skill in the art at the time the instant application was filed. Thus, one of ordinary skill, such as Huet, would have been able, without undue effort, to obtain the wild type sequence published by Balint for purposes of ascertaining if the claimed "single mutation" criteria were being met by a disputed ZYMV strain. In summary, the required frame of reference was readily apparent and available to those of ordinary skill 10 years before the time the application was filed in December 2000. The fact that the Balint reference was uncovered by

the Examiner in the course of Examination indicates that no undue effort is required to find it. Alternately, publication of the Huet reference in 1994 served to call attention to the Balint reference and make the required frame of reference publicly available six years before the filing date of the instant application.

Admittedly, Balint does not provide an electronic (read searchable) copy of the sequence. However, the full sequence was first published in 1995 [Wisler,G.C., Purcifull,D.E. and Hiebert,E. "Characterization of the P1 protein and coding region of the zucchini yellow mosaic virus" J of General Virology 76 37-45 (1995) [ACCESSION No. (L31350)]. (See appendix B) This publication made the required frame of reference even more "readily available" to "one of ordinary skill in the art" five years before the filing date of the instant application.

In summary, one of ordinary skill in the art would both understand what is the wild type frame of reference for ZYMV and be able to access an electronically searchable copy for purposes of comparison on the filing date of the application. Therefore, those of ordinary skill would not have thought that the Wild Type frame of reference would be at issue in December 2000 when the instant application was filed.

Applicant asserts that the Examiner's suggestion that failure to specifically define L31350 as the frame of reference represents an "error in judgment" on the part of the Applicant is indicative of an inability to grasp the

state of the art and the level of knowledge of one of "ordinary skill in the art" at the time the application was filed.

The Examiner has asserted that the "wide availability" of the Wisler reference has not been established. Such an assertion is not well taken. The Huet reference appears in the same journal [J. of Gen. Virol.] as the Wisler reference. Further, the required "frame of reference" is available though the NCBI search engine on the Internet [Appendix B].

Applicant notes, for the record, that the currently pending office action contains no request for a SEQ. ID. NO. Thus, the requisite frame of reference for a ZYMV with a single mutation is supplied by the Wisler reference. The mutation itself is described in detail in the body of claim 1, from which claim 6 depends.

The Examiner's rejection of claims 6, 10 and those portions of claims 12 and 20 which depend therefrom under 35 U.S.C. §112 is traversed.

A stipulation that these claims contain allowable subject matter is sought.

REJECTIONS UNDER 35 U.S.C. §102 (b)

The Examiner has rejected claims 1, 2, 6, 10-12, 15 and 20 under 35 U.S.C. §102 (b) as being anticipated by Huet.

Because the Applicant has not overcome the §112 second paragraph rejections for independent claim 1 and dependent claims 2, 11 and 15, no argument against the §102 (b) rejection of those claims is offered.

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The Examiner's rejection of dependent claims 6 and 10 and those portions of claims 12 and 20 which depend therefrom is not well taken.

Rejection of these claims as being anticipated by Huet in a previous office action induced the Applicant to offer substantive amendments which greatly reduced the scope of the claimed invention. Specifically, the phrase "a single mutation" meaning one and only one mutation was introduced into claim 1.

Huet teaches against what is claimed by teaching a ZYMV strain characterized by two mutations. Applicant asserts "a single mutation" as instantly claimed, is patentably distinct from the Huet teachings. Huet fails to hint or fairly suggest any necessity or advantage for isolating the claimed ARG to ILE mutation in the FRNK box from the "PAK" mutation described in figure 2; line 1 (p1410) of the Huet reference.

The Examiner's attempt to obfuscate the issue by referring to a "frame of reference" in the context of the 102(b) rejection is resented. Applicant's arguments concerning frame of reference are set forth hereinabove under the 112 second paragraph traversal.

Claim 6, which depends from claim 1, is directed towards a construct containing a single mutation. Applicant strongly asserts that this stipulation of "a single mutation" establishes metes and bounds which clearly exclude the 2-mutant construct described by Huet.

While the Huet reference is definitely appropriate to use in examining the instant application, any assertion that Huet anticipates the instantly claimed invention must ultimately be rejected. Huet observed certain properties in a mutant

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strain with 2 mutations. However, Huet does not hint or fairly suggest that the Arg to Ile mutation in the FRNK box <u>ALONE</u> is necessary or desirable to produce a:

"…construct is capable of systemic infection of a plant;

wherein said systemic infection induces a mild form of disease; and wherein said systemic infection affords cross protection against a subsequent potyvirus infection."

as instantly claimed.

Thus, the Examiner's assertion that "… the sequence taught by Huet et. al. meets the all of the limitations of the claims…" is erroneous on its face.
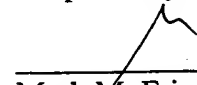
The Examiner's rejection of claims 6 and 10 and those portions of claims 12 and 20 which depend therefrom under 35 U.S.C. §102 (b) is traversed.

All rejections of claims 6 and 10 and those portions of claims 12 and 20 which depend therefrom are traversed.

All objections are refuted.

Claims 6 and 10 and those portions of claims 12 and 20 which depend therefrom contain patentable subject matter. Stipulation of allowable subject matter is respectfully requested so that Applicant can undertake to re-draft the claims in independent language.

Respectfully submitted,

Mark M. Friedman
Attorney for Applicant
Registration No. 33,883

Date: January 12, 2006

IX. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The text of the claims on appeal is:

1) (Previously Entered) A recombinant potyvirus infectious nucleic acid construct useful for plant cross protection, the construct comprising a full length clone characterized by a single mutation, said single mutation residing in its HC- Pro gene conserved FRNK box encoding sequence said single mutation encoding a substitution of Arg by Ile;

wherein the construct is capable of systemic infection of a plant;

wherein said systemic infection induces a mild form of disease; and

wherein said systemic infection affords cross protection against a subsequent potyvirus infection.

2) (Previously Entered) A recombinant construct according to claim 1 wherein the nucleic acid is cDNA or an RNA transcript.

3-5) (Cancelled)

6) (Previously Entered) A recombinant potyvirus infectious nucleic acid construct according to any of claims 1 and 2 wherein the potyvirus is ZYMV.

7-9) (Cancelled)

10)	(Previously Entered) A recombinant construct according to claim 6 wherein said cross protection is against severe strains of ZYMV.

11)	(Previously Entered) A recombinant potyvirus infectious nucleic acid construct according to any of claims 1, 2 and 6 wherein the potyvirus is selected from BCMV, BYMV, BtMV, MWMV, OYDV, PRSV, PStV, PepMoV, PVMV, CGVBV, GEV, ISMV, JGMV, LYSV, LMV, MDMV, PPV, PVA, PVV, PVY, SCMV, SPFMV, TEV, TVMV, TBV, TuMV, WMV-2, YMV and ZYFV.

12)	(Previously Entered) A recombinant construct according to any of claims 1, 2, 6, 10 and 11 further useful for the transient expression of foreign nucleic acid in plants wherein the full length clone has, in any position, a sequence of DNA or RNA inserted into the full length clone.

13-14)	(Cancelled)

15)	(Previously Entered) A method for introducing foreign nucleic acid into plants comprising infecting a plant with a recombinant potyvirus infectious nucleic acid construct as defined in claim 11.

16-19)	(Cancelled)

20)   (Previously Entered) Compositions for plant inoculation or for transient expression of foreign nucleic acid in plants containing, as an active ingredient, the recombinant construct according to any of claim 1, 2, 6, 10, 11 and 12.

X. APPENDIX OF EVIDENCE

NONE

XI. APPENDIX OF RELATED PROCEEDINGS

NONE

APPENDIX A TO SUPPLEMENTARY BRIEF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant: §
§
GAL-ON ET AL. §
§
Serial No.: 09/647,952 §
§
Filed: December 06, 2000 §   Group Art Unit: 1638
§
For: RECOMBINANT POTYVIRUS §   Attorney
CONSTRUCT AND USE §   Docket: was 1268-107
THEREOF §   now 1686/12
Examiner: DR. GEORGIA HELMER §

Because a written authorization for use of e-mail has been provided in this case in accord with MPEP 502.03, communications via Internet e-mail, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used. In such case, a printed copy of the Internet e-mail communications MUST be given a paper number, entered into the Patent Application Locating and Monitoring System (PALM) and entered in the patent application file.

TELEPHONE INTERVIEW SUMMARY

A telephone interview was conducted on Wed June 30 at 9 am Washington D.C. time. The USPTO was represented by Elizabeth McElwain and Georgia Helmer. The Applicant was represented by Sinai Yarus of Mark Friedman Ltd.

Current Status

An appeal brief was filed by Applicant's representative after a final action was received. The Examiner responded by issuing a non-final action. Applicant may either respond or request re-instatement of the appeal. Applicant requested, and was granted, an interview for the express purpose of avoiding re-instatement of appeal.

Substantive issues

Claim 1 as currently on record reads:

"A recombinant potyvirus infectious nucleic acid construct useful for plant cross protection, the construct comprising <u>a full length clone characterized by a single mutation</u>, said <u>single mutation</u> residing in its HC- Pro gene conserved FRNK box encoding sequence said single mutation encoding a substitution of Arg by Ile; ...

The Examiner has rejected the claim stating that a "frame of reference" for the whole "full length clone" is required.

While claim 1 as currently on file is for all potyviruses, the original appeal brief indicated that:

"Independent claim 1 and dependent claims 2, 11, 12, 15 and 20 are grouped together and will stand or fall together while dependent claims 6 and 10 are presented as a separate group which may stand independently of the other claims."

Claims 6 and 10 relate specifically to ZYMV as a subset of potyviruses.

The interview was directed primarily towards trying to agree on an acceptable frame of reference for claim 6.

Both sides referred to the Huet et al. reference (1994; J. Gen. Virol (75);1407-14) reference which is the sole prior art reference currently employed by the Examiner in formulating a rejection.

Applicant pointed out that Huet , being "one of ordinary skill in the art" in 1994, was aware of a published wild type sequence for ZYMV and cited same

(Balint et al. (1990) Proceedings of the VIIIth International Congress of Virology (abstract) Berlin; p472).

Applicant asserted that the Huet reference refers to Balint et al (1990) which discloses the full sequence of ZYMV making it publicly available and establishing the required frame of reference for claim 6. Applicant further argued that one of ordinary skill, such as Huet, would have been able, without undue effort, to obtain the wild type sequence published by Balint. As such, the required frame of reference was readily apparent and available to those of ordinary skill 10 years before the time the application was filed in December 2000.

The Examiner argued that Balint does not provide an electronic (read, searchable) copy of the sequence so that the required frame of reference is not available.

Applicant asserted that the full sequence was first published in 1995 [Wisler,G.C., Purcifull,D.E. and Hiebert,E. "Characterization of the P1 protein and coding region of the zucchini yellow mosaic virus" J of General Virolrology 76 37-45 (1995) [ACCESSION No. L31350)]. (See additional attached document downloaded from NCBI) Applicant further asserted that this publication made the required frame of reference "readily available" to "one of ordinary skill in the art" one year before the filing date of the instant application. This means that one of ordinary skill in the art would both understand what is the wild type frame of reference and be able to access an electronically searchable copy for purposes of comparison on the filing date of the application. Applicant further asserted that

those of ordinary skill would not have thought that the Wild Type frame of reference would be at issue in December 2000 when the application was filed.

The Examiner asserted that the "wide availability" of the Wisler Reference was not established. Applicant responded that while the J. of Gen. Virol. is not as widely distributed as the New York Times, it is well known to virologists of ordinary skill (e.g. Huet).

The Examiner asserted that even if the Wisler Reference were placed on the record it would still not establish the requisite frame of reference because it is not in the specification. Applicant countered by saying that the file wrapper in its entirety is available for inspection in cases where the meaning of a claim is at issue.

Applicant offered to file an IDS under Title 37 § 1,97(c)(2). (IDS after office action but before final action or notice of allowance) to get the Wisler reference "On the Record". Examiner asserted that this would not establish the requisite frame of reference.

The Examiner suggested alternate strategies for establishing the requisite frame of reference including:

1) Deposit in a recognized depository of ZYMV-AG1. The Examiner stipulated that introduction of a depoit number for this strain into the specification would be permissible because the strain was mentioned in the application as originally filed (e.g. in claim 7, now cancelled).

2) Submit of an affidavit from a disinterested party, even a colleague from the same institution as the inventor. Disinterested was defined as anyone that hold no rights in the application by virtue of assignment and is not an inventor. The affidavit should state that "At the time of filing of the application it was

well known that L31350 is the wild type sequence for ZYMV and thus establishes the appropriate frame of reference."

Applicant's representative inquired as to the time frame for processing a response and was informed that it was unlikely that any action in this case would be taken before the July 19 deadline for re-instating the appeal. This is apparently because the case is not currently the subject of a final action.

Applicant's representative undertook to communicate the substance of the interview to the Applicant.

Interview was conducted and concluded amicably, but without resolving the substantive issue of frame of reference.

This summary is not a response to the currently pending office action in this case and does not prejudice the Applicant's right to re-instate the appeal.

Interview duration; approximately 40 minutes

UNSIGNED E-MAIL TRANSMISSION

Dr. Sinai Yarus
Mark Friedman Ltd.

NCBI Nucleotide

Entrez   PubMed   Nucleotide   Protein   Genome   Structure   PMC   Taxonomy

Search Nucleotide ▼ for [   ] Go Clear

Limits   Preview/Index   History   Clipboard   Deta

Display default ▼ Show: 20 ▼ Send to File Text Clipboard   Get Subsequence

☐ **1: L31350**. Zucchini yellow m...[gi:466347]   Links

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LOCUS       ZYMPROPOLR              9593 bp ss-RNA     linear   VRL 28-APR-1995
DEFINITION  Zucchini yellow mosaic virus polyprotein, complete cds; P1
            protease; P2 HC-protease; cylindrical inclusion protein; protease;
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ACCESSION   L31350
VERSION     L31350.1  GI:466347
KEYWORDS    capsid protein; cylindrical inclusion protein; polyprotein;
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SOURCE      Zucchini yellow mosaic virus
  ORGANISM  Zucchini yellow mosaic virus
            Viruses; ssRNA positive-strand viruses, no DNA stage; Potyviridae;
            Potyvirus.
REFERENCE   1  (bases 1 to 9593)
  AUTHORS   Wisler,G.C., Purcifull,D.E. and Hiebert,E.
  TITLE     Characterization of the P1 protein and coding region of the
            zucchini yellow mosaic virus
  JOURNAL   J. Gen. Virol. 76 (Pt 1), 37-45 (1995)
  MEDLINE   95146958
   PUBMED   7844540
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